



The Gambia Pneumococcal Vaccine Trial

BACKGROUND ABOUT THE TRIAL



As in many developing countries, children in The Gambia have been disproportionately affected by pneumococcal diseases. Infant and child mortality rates in The Gambia are high, acute respiratory infections are a leading cause of death, and the

pneumococcus is the most common cause of these severe infections. Preventing diseases caused by *Streptococcus pneumoniae* is therefore an important strategy for improving child survival.

The Gambia is a small country on the west coast of Africa, surrounded by the Republic of Senegal on three sides, and divided by the River Gambia that gives the country its name. In many ways The Gambia is typical of much of sub-Saharan Africa. The majority of the country's 1.4 million people live in rural areas and survive on subsistence agriculture. As in many developing countries, literacy rates are low, and infrastructure is limited, as is access to health care. Unlike some developing countries, however, there is high coverage of *Haemophilus influenzae* type b, diphtheria, tetanus and pertussis, and measles vaccines, thus other major causes of severe pneumonia are already prevented by vaccination.

Over the years, The Gambian government, in conjunction with other partners, has conducted several large-scale studies of potentially life-saving interventions, including studies of vaccines, to protect its population from diseases such as hepatitis B, *Haemophilus influenzae* type B, malaria, and pneumococcal infections.

To respond to the threat of pneumococcal infections in children, The Gambian government and the British Medical Research Council (MRC) conducted a study of a vaccine containing polysaccharides from nine subtypes of pneumococcal bacteria. This study was carried out as a partnership of many organizations. At a planning level, working groups of government health officials from The Gambia and the MRC laid the groundwork for the study and provided oversight of the trial. On the front lines, MRC nurses and field staff worked side-by-side with Gambian government health employees such as vaccination clerks and nurses to recruit, vaccinate, treat, and follow-up study participants. An international steering committee, appointed by the World Health Organization and including the Director of Medical Services from The Gambian government and international experts in vaccines and public health, provided additional oversight of the study's scientific quality. Independent monitors audited the conduct of the trial regularly, according to international guidelines for conduct of clinical trials.

The study was supported by a broad coalition of international partners including the National Institute of Allergy and Infectious Diseases/National Institutes of Health; the British Medical Research Council/United Kingdom; the London School of Hygiene and Tropical Medicine; the World Health Organization; the U.S. Agency for International Development; the U.S. Centers for Disease Control and Prevention; Wyeth-Lederle Vaccines; and the Program for Appropriate Technology in Health (PATH) Children's Vaccine Program. See the accompanying press release for information about study results.